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EXAMINER

HUANG, EVELYN MEI

| | |
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| ART UNIT | PAPER NUMBER |
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1625

DATE MAILED: 04/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,926

Applicant(s)

ZHI ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 23-26, 30-52, 55, 57-63 and 98-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 23-26, 30-39, 42-52, 55, 57-63, 98-107 is/are rejected.
- 7) ☒ Claim(s) 40 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1 Claims 1-17, 23-26, 30-52, 55, 57-63, 98-107 are pending.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-21-2005 has been entered.

Election/Restrictions

3. In response to the restriction requirement mailed on 1-13-2003, Applicant has elected with traverse the compound of Group III, claims 1-63. The species elected is Example 53 on page 68 of the specification, which reads on claims 1-2, 4-11, 18-19, 21-22, 27-38, 40-49, 53-54, 56-63 and the structural formula (I). Claims of the other groups are withdrawn from further consideration as being drawn to the non-elected inventions. The search has been conducted to the species compound, and its generic structural formula (I), and extended to structural formulae (II) -(IV). Claims of the other groups are withdrawn from further consideration as being drawn to the non-elected inventions. Claims directed to compounds outside of the formulae (I) -(IV) are withdrawn from further consideration.

For claims 1-17, 23-26, 30-52, 55, 57-63, 98-107, the restriction requirement is restated as follows:

- | | |
|-----------|---|
| Group I. | Claims 1-17, 23-26, 30-52, 55, 57-63, 98-107 in part, drawn to a compound of formulae I to IV, and the composition thereof. |
| Group II. | Claims 1-17, 23-26, 30-52, 55, 57-63, 98-107, drawn to a compound of formulae V to VIII, and the composition thereof. |

The Group I compounds and the Group II compounds are structurally, chemically and patentably distinct. A reference anticipating the Group I compound would not render obvious the Group II compounds. Restriction as indicated is therefore proper.

Applicants have elected Group I based on the elected species of Example 53 on page 68 of the specification. Claims directed to compounds outside of the formulae (I) -(IV), i.e. Group II, are withdrawn from further consideration as being drawn to the non-elected invention.

Claim Rejections - 35 USC § 112

4. The rejection for Claims 18-22, 27, 28, 56, 53 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is rendered moot by the cancellation of these claims.

Duplicate Claims

5. The cancellation of Claims 19, 22, 28 has rendered moot the objection to its being a substantial duplicate of claim 1.

Claim Rejections - 35 USC § 102

6. The rejection for Claims 1, 2, 4-11, 14-19, 21-39 under 35 U.S.C. 102(b) as being anticipated by Yamashkin et al. (Chemistry of Heterocyclic Compounds (New York)(Translation of Khimiya Geterotsiklicheskikh Soedinenii) (1999), Volume Date 1998, 34(9), 1050-1065, abstract) is withdrawn in view of the amendment deleting H, methyl and unsubstituted alkyl from the definition of R₂, thereby setting a demarcation from the prior art compound.

7. The rejection for Claims 1, 2, 4-11, 14-19, 21-39 under 35 U.S.C. 102(b) as being anticipated by El-Desoky (Zeitschrift fuer Naturforschung, B: Chemical Sciences (1998), 53(10),

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1216-1222, abstract) is withdrawn in view of the amendment deleting H, methyl and unsubstituted alkyl from the definition of R2, thereby setting a demarcation from the prior art compound.

8. The rejection Claims 1, 2, 4-11, 14-19, 21-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Majumdar et al. (Journal of Chemical Research, Synopses (1997), (9), 310-311, abstract) is withdrawn in view of the amendment deleting H, methyl and unsubstituted alkyl from the definition of R2, thereby setting a demarcation from the prior art compound.

9. The rejection for Claims 1, 2, 4-11, 14-19, 21-39 under 35 U.S.C. 102(b) as being anticipated by Yamashkin et al. (Khimiya Geterotsiklicheskikh Soedinenii (1983), (4), 493-7, abstract) is withdrawn in view of the amendment deleting H, methyl and unsubstituted alkyl from the definition of R2, thereby setting a demarcation from the prior art compound.

10. The rejection for Claims 1, 2, 4-11, 14-19, 21-39 under 35 U.S.C. 102(b) as being anticipated by Akhvlediani et al. (Zhurnal Organicheskoi Khimii (1981), 17(7), 1542-6, abstract) is withdrawn in view of the amendment deleting H, methyl and unsubstituted alkyl from the definition of R2, thereby setting a demarcation from the prior art compound.

Claim Rejections - 35 USC § 103

11. The rejection for Claims 1-11, 14-19, 21-38, 42-51, 53-62 under 35 U.S.C. 103(a) as being unpatentable over Adams (WO 00/12502) is withdrawn in view of the amendment deleting H, methyl and unsubstituted alkyl from the definition of R2, thereby setting a further demarcation from the prior art compound wherein R2 and R11 are H. Motivation to modify the prior art compound via multiple changes to arrive at the instant invention is lacking.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-11, 36-39, 46-47, 60-63, 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 9, 36, R1 as unsubstituted alkyl has no antecedent basis in the base claim 1, wherein only substituted alkyl is recited.
- b. Claims 46, 60, R2 as H has no antecedent basis in the base claim 42, wherein H has been deleted from the definition of R2.
- c. Claim 99, the 'carrier' has no antecedent basis in the base claim 98, which is a compound claim.

The rejection is applicable to claims dependent on the above claims.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17, 23-26, 30-39, 42-52, 55, 57-63, 98-107 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Formulae III and IV in claim 1, 42 are not described in the specification or the original claims.

The court has held that 'whatever may be the viability of an inductive-deductive approach to arriving at a claimed subgenus, it cannot be said that such a subgenus is necessarily

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described by a genus encompassing it and a species upon which it reads.” In re Wilder, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984). See MPEP 2163.05.

A description of R1 and/or R2 being a ‘substituted alkyl’ as in the amended claims 1, 42 is not found in the specification, especially when a species compound having a ‘substituted alkyl’ is not described in the specification.

A description of R2 being an alkyl selected from ethyl, n-propyl, isopropyl etc. as recited in the new claim 98 is not found in the specification, especially when a species compound having a R2 substituents falling within the recited genus is not described in the specification.

The rejection is applicable to claims dependent on the above claims.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17, 23-26, 30-39, 42-52, 55, 57-63, 98-107 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for compounds wherein R4 and R6 together or R6 and R8 together form a heterocyclic ring or compounds wherein the adjacent R3-R8 are all optionally substituted aryl or heteroaryl. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

a. *Nature of the invention.*

The instant invention is drawn to a nitrogen containing tricyclic heterocyclic androgen receptor modulating compound, and the composition thereof.

b. *Predictability/unpredictability of the art.*

Unlike the mechanical art, the high degree of unpredictability is well recognized in the chemical synthetic art. A change in the structure of the compound may drastically affect the rate of the chemical reaction.

c. *Amount of guidance/working examples.*

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The preparation of example compounds is limited to compounds wherein R1 is H, R2 is CF3, R3-R8 are acyclic substituents or one of R5 or R6 is aryl, or R4 and R6 together, or R6 and R8 together form a carbocyclic ring.

Compounds wherein the adjacent R3-R8 are all optionally substituted aryl or heteroaryl, or compounds wherein R4 and R6 together, or R6 and R8 together form a heterocyclic ring are structurally quite removed from the example compounds. Starting materials and process of making these compounds are not seen but required. Sources are particularly pertinent because absent sources, the public is offered mere language, rather than enablement. Ex parte Moersch 104 USPQ 122. In re Howarthe 210 USPQ 689.

d. *The breadth of the claims.*

Applicant's assertion that the processes and starting materials used for the preparation of the example compounds would be applicable for the preparation of all the structurally diverse compounds of formulae I-IV, especially those compounds wherein the adjacent R3-R8 are all optionally substituted aryl or heteroaryl, or compounds wherein R4 and R6 together, or R6 and R8 together form a heterocyclic ring, does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability in the art and the limited working examples (paragraphs b, c above).

e. *Quantitation of undue experimentation.*

Since insufficient teaching and guidance have been provided in the disclosure, one of ordinary skill in the art, would not be able to make and use all the compounds as claimed without undue experimentation.

Allowable Subject Matter

15. The compounds of formula I to IV in Claims 40-41, and the composition thereof, are allowable. These claims are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


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The instant compounds having a 3-2,2,2-trifluoroethyl and a 9-trifluoromethyl are not taught or suggested by the above references. Motivation to modify the prior art compound to arrive at the instant is lacking.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang
Primary Examiner
Art Unit 1625